DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

2356 ST-1

SEP 29

Abbott Laboratories
Attention: Leslie R. Koehler
D-389, Building AP30
200 Abbott Park Road
Abbott Park, IL 60064-3537

Docket No. 98P-0821/CP1

Dear Ms. Koehler:

This is in response to your petition filed on September 25, 1998, and your amendment dated December 4, 1998, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydromorphone Hydrochloride Injection, 0.2 mg/mL, 30 mL vials. The listed drug product to which you refer in your petition is Dilaudid-HP ® (Hydromorphone Hydrochloride) Injection, 10 mg/mL, 5 mL ampoules and 50 mL vials manufactured by Knoll Pharmaceuticals.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Your request involves a change in strength and route of administration from that of the listed drug product (i.e., from 10 mg/mL to 0.2 mg/mL, and from an injection that is administered by the subcutaneous, intramuscular, and intravenous route to one that is administered by the subcutaneous and intravenous route). The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

Under Sections 505(j)(2)(C)(i) of the Act the Agency must approve a petition seeking a change in strength and a change in route of administration unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage strength and the differing route of administration.

The Agency has determined that your proposed changes in strength and route of administration raise questions of safety and effectiveness because: (1) The proposed product is likely to find use in different patient populations than the reference listed drug is approved for. (2) The proposed product appears to be suitable for use post-operatively in patient controlled analgesia (PCA) which is a different indication than that approved for the reference listed drug. (3) The product appears to be unsuitable for subcutaneous administration because of the volume of fluid required. Thus the Agency has concluded that clinical trials are required for this specific drug product. In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in route of

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administration is subject to the Pediatric Rule and has concluded that investigations are necessary to demonstrate the safety and effectiveness in the pediatric population. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product.

Please contact the Division of Anesthetic, Critical Care, and Addiction Drug Products at (301) 827-7410 for information regarding the types of studies necessary to support the approval of your proposed drug product.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research